

DETAILED ACTION

This action is in response to the amendment filed on 9/29/11. Currently, claims 19-68 and 70-83 are pending in the application. Claims 19-31, 41-47, 58-65 and 70-73 were withdrawn by Applicant and claims 1-18 and 69 were cancelled by Applicant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 32-34, 40, 48-52, 55, 57, 66, 68, 74 and 75 are rejected under 35 U.S.C. 102(e) as being anticipated by Schweich, Jr. et al. (US 5,961,440).

In regards to claim 32, Schweich, Jr. et al. teaches in Figure 1, the abstract and column 2, lines 56-59 a shaft (18) configured for transmucosal insertion into a soft tissue located in a patient's oral cavity or pharynx; a retractor member (20) connected at or near a first end of the shaft (18); and an anchor member (20) connected at or near a second end of the shaft (18), wherein at least one of the retractor member (20) or the anchor member (20) is configured to be positioned on an external surface of the soft tissue, neither the retractor member (20) nor the anchor member (20) configured to be tethered to bone, and at least one of the shaft (18), the retractor member (20) and the

anchor member (20) interact to exert a pressure that prevents the deformation of the external surface of the soft tissue.

In regards to claim 33, Schweich, Jr. et al. teaches the apparatus of claim 32. Schweich, Jr. et al. teaches in Figure 1, the abstract and column 2, lines 56-59 that the pressure can stiffen the soft tissue (by exerting pressure on the soft tissue to secure it in place) to prevent deformation of the external surface, the pressure is a counterforce pressure that prevents deformation of the external surface, the pressure is a counterforce pressure that creates an indentation in the external surface, or at least one of the retractor member (20), the shaft (18), and the anchor member (20) adjust to alter the pressure exerted on the soft tissue.

In regards to claim 34, Schweich, Jr. et al. teaches the apparatus of claim 32. Schweich, Jr. et al. teaches in column 7, lines 31-33 that the shaft (tension member 18) is flexible.

In regards to claim 40, Schweich, Jr. et al. teaches the apparatus of claim 32. Schweich, Jr. et al. teaches in Figure 1 a connection configured to couple to at least one of the patient's pharynx, the patient's oral cavity, the patient's tooth, a dental device, and a mount (14) exterior to the patient's mouth.

In regards to claim 48, Schweich, Jr. et al. teaches in Figure 1, the abstract and column 2, lines 56-59 a shaft (18) configured for transmucosal insertion into a patient's tongue; a retractor member (20) connected at or near a first end of the shaft (18); and an anchor member (20) connected at or near a second end of the shaft (18), wherein at least one of the retractor member (20) or the anchor member (20) is configured to be

positioned on an external surface of the tongue, neither the retractor member (20) nor the anchor member configured to be tethered to bone, and at least one of the shaft (18), the retractor member (20) and the anchor member (20) interact to exert a pressure that prevents the external surface from falling toward a soft tissue located in the patient's oral cavity or pharynx.

In regards to claim 49, Schweich, Jr. et al. teaches the apparatus of claim 48. Schweich, Jr. et al. teaches in Figure 1 that the shaft (18) is sized for insertion through the patient's tongue.

In regards to claim 50, Schweich, Jr. et al. teaches the apparatus of claim 48. Schweich, Jr. et al. teaches in Figure 1, the abstract and column 2, lines 56-59 that the pressure can stiffen the soft tissue (by exerting pressure on the soft tissue to secure it in place) to prevent deformation of the external surface, the pressure is a counterforce pressure that prevents deformation of the external surface, the pressure is a counterforce pressure that creates an indentation in the external surface, or at least one of the retractor member (20), the shaft (18), and the anchor member (20) adjust to alter the pressure exerted on the soft tissue.

In regards to claim 51, Schweich, Jr. et al. teaches the apparatus of claim 48. Schweich, Jr. et al. teaches in column 7, lines 28-30 that the tissue retractor is formed from one of more biocompatible materials.

In regards to claim 52, Schweich, Jr. et al. teaches the apparatus of claim 48. Schweich, Jr. et al. teaches in column 7, lines 31-33 that the shaft (tension member 18) is flexible.

In regards to claim 55, Schweich, Jr. et al. teaches the apparatus of claim 48. Schweich, Jr. et al. teaches in Figure 1 an apparatus in which the external surface can be the centerline of the tongue curve.

In regards to claim 57, Schweich, Jr. et al. teaches the apparatus of claim 48. Schweich, Jr. et al. teaches in Figure 1 a connection configured to couple to at least one of the patient's pharynx, the patient's oral cavity, the patient's tooth, a dental device, and a mount (14) exterior to the patient's mouth.

In regards to claim 66, Schweich, Jr. et al. teaches in Figure 1, the abstract and column 2, lines 56-59 a shaft (18) configured for transmucosal insertion into a patient's tongue; a retractor member (20) connected at or near a first end of the shaft (18), and an anchor member (20) connected at or near a second end of the shaft (18), wherein at least one of the retractor member (20) or the anchor member (20) is configured to be positioned on an external surface of the tongue, neither the retractor member (20) nor the anchor member (20) configured to be tethered to bone, and at least one of the shaft (18), the retractor member (20) and the anchor member (20) configured to prevent at least a portion of the tongue from collapsing toward a soft tissue located in the patient's oral cavity or pharynx.

In regards to claim 68, Schweich, Jr. et al. teaches in Figure 1, the abstract and column 2, lines 56-59 a shaft (18) configured for transmucosal insertion into the soft tissue; a retractor member (20) connected at or near a first end of the shaft (18); and an anchor member (20) connected at or near a second end of the shaft (18), wherein the retractor member (20) and the anchor member (20) are configured to maintain a

position on an external surface of the soft tissue, and the shaft (18), the retractor member (20) and the anchor member (20) interact to exert a pressure that prevents the deformation of the external surface of the soft tissue.

In regards to claim 74, Schweich, Jr. et al. teaches in Figure 1, the abstract and column 2, lines 56-59 the device having a first end, a second end, and a shaft (18) disposed therebetween, the shaft (18) is adapted for transmucosal insertion through a soft tissue located in the patient's oral cavity or pharynx, with at least one of the first end and the second end able to be positioned on an external surface of the soft tissue with each of the first end and the second end configured to contact solely soft tissue, and with at least one of the first end, the second end, and the shaft (18) able to interact to exert a pressure that prevents deformation of at least a portion of the soft tissue to prevent obstruction in the patient's airway.

In regards to claim 75, Schweich, Jr. et al. teaches the apparatus of claim 74. Schweich, Jr. et al. teaches in Figure 1 that both the first and the second end are configured to be positioned on an external surface of the soft tissue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 35, 37, 53, 56, 67 and 76-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schweich, Jr. et al. (US 5,961,440).

In regards to claim 35, Schweich, Jr. et al. teaches the apparatus of claim 32. Schweich, Jr. et al. discloses the claimed invention except for the shaft being removable from the soft tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the shaft removable from the soft tissue, since it has been held that the separation of elements, where removability would be desirable, is a design consideration within the skill of the art. *In re Dulberg*, 283 F. 2d 522, 129 USPQ 348 (CCPA 1961).

In regards to claim 37, Schweich, Jr. et al. teaches the apparatus of claim 32. Schweich, Jr. et al. discloses the claimed invention except for at least one of the retractor member and the anchor member being disengagable from the shaft. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make at least one of the retractor member and the anchor member being disengagable from the shaft, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicnram*, 168 USPQ 177, 179.

In regards to claim 53, Schweich, Jr. et al. teaches the apparatus of claim 48. Schweich, Jr. et al. discloses the claimed invention except for the shaft being removable from the patient' tongue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the shaft removable from the patient's tongue, since it has been held that the separation of elements, where removability

would be desirable, is a design consideration within the skill of the art. *In re Dulberg*, 283 F. 2d 522, 129 USPQ 348 (CCPA 1961).

In regards to claim 56, Schweich, Jr. et al. teaches the apparatus of claim 48. Schweich, Jr. et al. discloses the claim invention except for at least one of the retractor member and the anchor member being disengagable from the shaft. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make at least one of the retractor member and the anchor member being disengagable from the shaft, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicnrm*, 168 USPQ 177, 179.

In regards to claim 67, Schweich, Jr. et al. teaches the apparatus of claim 66. Schweich, Jr. et al. discloses the claim invention except for the shaft being removable from the patient's tongue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the shaft removable from the patient's tongue, since it has been held that the separation of elements, where removability would be desirable, is a design consideration within the skill of the art. *In re Dulberg*, 283 F. 2d 522, 129 USPQ 348 (CCPA 1961).

In regards to claim 76, Schweich, Jr. et al. teaches the apparatus of claim 32. Schweich, Jr. et al. does not teach that the tissue retractor is adjustable. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the tissue retractor adjustable, since it has been held that the

provision of adjustability, where needed, involves routine skill in the art. *In re Stevens*, 101 USPQ 284 (CCPA 1954).

In regards to claim 77, Schweich, Jr. et al. teaches the apparatus of claim 32. Schweich, Jr. et al. does not teach that the anchor member is detachable from the shaft. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the anchor member being detachable from the shaft, since it has been held that the separation of elements, where removability would be desirable, is a design consideration within the skill of the art. *In re Dulberg*, 283 F. 2d 522, 129 USPQ 348 (CCPA 1961).

In regards to claim 78, Schweich, Jr. et al. teaches the apparatus of claim 48. Schweich, Jr. et al. does not teach that the tissue retractor is adjustable. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the tissue retractor adjustable, since it has been held that the provision of adjustability, where needed, involves routine skill in the art. *In re Stevens*, 101 USPQ 284 (CCPA 1954).

In regards to claim 79, Schweich, Jr. et al. teaches the apparatus of claim 48. Schweich, Jr. et al. does not teach that the anchor member is detachable from the shaft. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the anchor member being detachable from the shaft, since it has been held that the separation of elements, where removability would be desirable, is a design consideration within the skill of the art. *In re Dulberg*, 283 F. 2d 522, 129 USPQ 348 (CCPA 1961).

In regards to claim 80, Schweich, Jr. et al. teaches the apparatus of claim 66. Schweich, Jr. et al. does not teach that the tissue retractor is adjustable. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the tissue retractor adjustable, since it has been held that the provision of adjustability, where needed, involves routine skill in the art. *In re Stevens*, 101 USPQ 284 (CCPA 1954).

In regards to claim 81, Schweich, Jr. et al. teaches the apparatus of claim 66. Schweich, Jr. et al. does not teach that the anchor member is detachable from the shaft. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the anchor member being detachable from the shaft, since it has been held that the separation of elements, where removability would be desirable, is a design consideration within the skill of the art. *In re Dulberg*, 283 F. 2d 522, 129 USPQ 348 (CCPA 1961).

In regards to claim 82, Schweich, Jr. et al. teaches the apparatus of claim 68. Schweich, Jr. et al. does not teach that the tissue retractor is adjustable. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the tissue retractor adjustable, since it has been held that the provision of adjustability, where needed, involves routine skill in the art. *In re Stevens*, 101 USPQ 284 (CCPA 1954).

In regards to claim 83, Schweich, Jr. et al. teaches the apparatus of claim 68. Schweich, Jr. et al. does not teach that the anchor member is detachable from the shaft. However, it would have been obvious to one having ordinary skill in the art at the time

the invention was made to provide the anchor member being detachable from the shaft, since it has been held that the separation of elements, where removability would be desirable, is a design consideration within the skill of the art. In re Dulberg, 283 F. 2d 522, 129 USPQ 348 (CCPA 1961).

3. Claims 36, 38, 39 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schweich, Jr. et al. (US 5,961,440) in view of Boretos (US patent 4,254,774).

In regards to claim 36, Schweich, Jr. et al. teaches the apparatus of claim 32. Schweich, Jr. et al. does not teach that at least one of the retractor member, the shaft, and the anchor member comprises an inflatable tube. However, Boretos teaches in column 3, lines 21-27 and column 4, lines 34-35 an analogous device in which at least one of the retractor member, the shaft, and the anchor member comprises an inflatable tube (12). It would have been obvious to one having ordinary skill in the art at the time of invention to modify the retractor member, the shaft or the anchor taught by Schweich, Jr. et al. with the inflatable tube taught by Boretos because this element is known to facilitate insertion and placement, as Boretos teaches in column 3, lines 21-27.

In regards to claim 38, Schweich, Jr. et al. teaches the apparatus of claim 32. Schweich, Jr. et al. does not teach that the shaft comprises an internal passageway for adding fluid. However, Boretos teaches in column 6, lines 30-33 an analogous device in which the shaft (11) comprises an internal passageway for adding fluid (gas). It would have been obvious to one having ordinary skill in the art at the time of invention

to modify the shaft taught by Schweich, Jr. et al. as modified by Boretos with the internal passageway for adding fluid taught by Boretos because this element is known to provide for a change in shape of the shaft taught by Schweich, Jr. et al., as Boretos teaches in column 5, lines 64-67.

In regards to claim 39, Schweich, Jr. et al. and Boretos teach the apparatus of claims 32 and 38. Schweich, Jr. et al. does not teach that the shaft comprises a regulator for said fluid. However, Boretos teaches in column 5, lines 64-67 and column 4, lines 30-33 an analogous device in which the shaft (11) comprises a regulator (21) for said fluid gas. It would have been obvious to one having ordinary skill in the art at the time of invention to modify the shaft taught by Schweich, Jr. et al. as modified by Boretos with the regulator taught by Boretos because this element is known to control the change in shape and size produced by the influx of fluid into the shaft.

In regards to claim 54, Schweich, Jr. et al. teaches the apparatus of claim 48. Schweich, Jr. et al. does not teach that at least one of the retractor member, the shaft, and the anchor member comprises an inflatable tube, or that the shaft comprises an internal passageway for adding a fluid. However, Boretos teaches in column 6, lines 30-33 an analogous device in which the shaft (11) comprises an internal passageway for adding a fluid (gas). It would have been obvious to one having ordinary skill in the art at the time of invention to modify the shaft taught by Schweich, Jr. et al. with the internal passageway for adding a fluid taught by Boretos because this element is known to provide for a change in shape of the shaft taught by Schweich, Jr. et al., as Boretos teaches in column 5, lines 64-67.

Response to Arguments

Applicant's amendments to claims 40 and 57 are sufficient to overcome the rejection of claims 40 and 57 under 35 U.S.C. 101. Applicant's amendment to claim 66 is sufficient to overcome the rejection of claims 66, 80 and 81 under 35 U.S.C. 101. Applicant's amendment to claim 74 is sufficient to overcome the rejection of claims 74 and 75 under 35 U.S.C. 101.

Applicant's arguments filed 9/29/11 have been fully considered but they are not persuasive. In response to applicant's argument that the device of Schweich, Jr. et al. is not configured for transmucosal insertion into the soft tissue, the examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the present case, the device of Schweich, Jr. et al. is **capable of** transmucosal insertion into the soft tissue inasmuch as an incision could be made to permit transmucosal insertion of the device of Schweich, Jr. et al. into the soft tissue.

In response to Applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the device must allow for fluid drainage from the insertion to prevent infection) are not recited in the rejected claim(s). Although the claims are interpreted in light of

the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA J. HICKS whose telephone number is (571)270-7033. The examiner can normally be reached on Monday through Thursday, 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. J. H./
Examiner, Art Unit 3772
10/6/11

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772